IFW 1624

PATENT
Attorney Docket **056291-5188 US**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Ingemar Starke *et al.***	)	Confirmation No. **4986**
Application No. **10/518,010**	)	Group Art Unit: **1624**
Filed: **December 14, 2004**	)	Examiner: **Brenda L. Coleman**
For: **Chemical Compounds**	)	Date: August 10, 2006

U.S. Patent and Trademark Office
Customer Service Window, **Mail Stop Amendment**
Randolph Building
401 Dulany Street
Alexandria, VA 22314

TRANSMITTAL FORM

1. Transmitted herewith is an Amendment and Response Under 37 C.F.R. 1.111 in response to the non-final Office Action dated April 10, 2006.

2. Additional Papers Submitted:
(i) English language abstract of Nippon Rinsho (Jan. 2002) 60(1):130-6
(ii) AstraZeneca Development Pipeline: NCEs and line extensions (July 28, 2005)

3. Extension of Time: The proceedings herein are for a patent application and the provisions of 37 C.F.R. 1.136(a) apply. Applicants petition for a one-month extension of time from July 10, 2006 to August 10, 2006, the fee for which is **$120.00** as set out in 37 C.F.R. 1.17(a). If Applicants have inadvertently overlooked the need for an additional extension of time, please consider this a petition therefore. The Commissioner is hereby authorized to charge any additional fees which may be required, including fees due under 37 C.F.R. 1.16 and 1.17, or credit any overpayment to Deposit Account 50-0310.

4. Transmitted herewith is a Terminal Disclaimer over U.S. Patent Application No. 10/502,355 ("the '355 application"). Applicants note for the record that under MPEP 804.02, the filing of this terminal disclaimer is not intended to be an admission that Applicants' claimed subject matter is not patentably distinct over the claimed subject matter in the '355 application. Rather, the filing of the terminal disclaimer "simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection" (citing *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870 (Fed. Cir. 1991)).

5. Transmitted herewith is a Terminal Disclaimer over U.S. Patent Application No. 10/488,540 ("the '540 application"). Applicants note for the record that under MPEP 804.02, the filing of this terminal disclaimer is not intended to be an admission that Applicants' claimed subject matter is not patentably distinct over the claimed subject matter in the '540 application. Rather, the filing of the terminal disclaimer "simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection" (citing *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870 (Fed. Cir. 1991)).

5. Transmitted herewith is a Terminal Disclaimer over U.S. Patent Application No. 10/451,262 ("the '262 application"). Applicants note for the record that under MPEP 804.02, the filing of this terminal disclaimer is not intended to be an admission that Applicants' claimed subject matter is not patentably distinct over the claimed subject matter in the '262 application. Rather, the filing of the terminal disclaimer "simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection" (citing *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870 (Fed. Cir. 1991)).

6. Fee Calculation (37 C.F.R. 1.16):

CLAIMS AS AMENDED						
	Remaining		**Previously Paid**	**Extra**	**Rate**	**Total Fees**
Total Claims	**13**	minus	**23**	**0**	$50.00 each=	0.00
Independent Claims	**2**	minus	**5**	**0**	$200.00 each=	0.00
First presentation of Multiple dependent claim					$360.00	0.00
					Sub-total =	0.00
					Reduction by ½ for filing by a small entity	0.00
					Total Fee =	$0.00

7. Fee Payment: The Commissioner is hereby authorized to charge **$510.00** to Deposit Account No. 50-0310 for payment of the One-Month Extension of Time Fee ($120.00), the Terminal Disclaimer Fee Under 37 C.F.R. 1.20(d) (Application No. 10/518,010) ($130.00), the Terminal Disclaimer Fee Under 37 C.F.R. 1.20(d) (Application No. 10/488,540) and the Terminal Disclaimer Fee Under 37 C.F.R. 1.20(d) (Application No. 10/451,262).

8. Constructive Petition: **Except** for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment

to Deposit Account 50-0310. This paragraph is intended to be a **constructive petition for extension of time** in accordance with 37 C.F.R. 1.136(a)(3).

Respectfully submitted,
Morgan, Lewis & Bockius LLP

Dated: **August 10, 2006**
Morgan, Lewis & Bockius LLP
Customer No. **09629**
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
202-739-3000

Gregory T. Lowen
Registration No. 46,882

Note: Performing your original search, ***ibat inhibitors*** , in PubMed will retrieve *29* citations.

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1: Nippon Rinsho. 2002 Jan;60(1):130-6.

Related Articles, Links

[Hypolipidemic drugs--ileal Na+/bile acid cotransporter inhibitors (S-8921 etc)]

[Article in Japanese]

Ichihashi T.

Developmental Research Laboratories, Shionogi & Co. LTD.

The ileal Na+/bile acid cotransporter (IBAT) maintains the reabsorption of bile acids from the ileum in the enterohepatic circulation of bile acids. Interruption of the enterohepatic circulation of bile acids by bile acid sequestrants or partial ileal bypass surgery can cause a significant decrease of serum cholesterol in animals and human patients. Inhibition of IBAT by specific IBAT inhibitors such as S-8921 has been proven to lower serum cholesterol in a variety of experimental animals. IBAT inhibitors, a new class of hypocholesterolemic drugs may be used alone or in combination with HMG-CoA reductase inhibitors in the treatment of hypercholesterolemia with low dosage and high compliance.

Publication Types:

- Review

PMID: 11808323 [PubMed - indexed for MEDLINE]

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AstraZeneca Development Pipeline: NCEs and line extensions
28 July 2005

Cardiovascular

Compound	Mechanism	Area under investigation	Phase	Estimated Filing	
				MAA	NDA
Exanta	thrombin inhibitor	prevention of VTE	III	Launched	Filed*
Exanta SC formulation	thrombin inhibitor (s.c)	prevention of VTE	III	Launched	>2007
Galida	PPAR agonist	diabetes /metabolic syndrome	III	2007	2007
AZD6140	ADP receptor antagonist	arterial thrombosis	II	>2007	>2007
AZD7009	Anti-arrhythmic IV	atrial fibrillation – conversion	II	>2007	>2007
AZD7009	Anti-arrhythmic oral	atrial fibrillation – maintenance	II	>2007**	>2007**
AZD9684	CPU inhibitor	thrombosis	II	>2007	>2007
AZD0837	thrombin inhibitor	thrombosis	II	>2007	>2007
AZD7806	IBAT inhibitor	dyslipidaemia	I	>2007	>2007
AZD4619		dyslipidaemia	I	>2007	>2007
AZD6610		dyslipidaemia/ diabetes	I	>2007	>2007
AZD8677		dyslipidaemia/ diabetes	I	>2007	>2007
AZD8294		dyslipidaemia	PC	>2007	>2007
AZD8450		dyslipidaemia	PC	>2007	>2007
AZD6370		diabetes	PC	>2007	>2007
AZD8593		haemostasis	PC	>2007	>2007
AVP 26452	Reverse Cholesterol Transport enhancer	dyslipidaemia	PC	>2007	>2007

*** project on hold while early Phase II data are reviewed*

Line Extensions

Atacand	angiotensin II antagonist	CHF outcomes (CHARM study)	III	Launched	Launched
Atacand	angiotensin II antagonist	diabetic retinopathy	III	> 2007	>2007
Crestor	statin	atheroma	III	2H2006	2H2006
Crestor	statin	outcomes CHF	III	>2007	>2007
Crestor	statin	outcomes Renal	III	2007	2007
Seloken/Toprol-XL	beta-blocker	HCTZ combination	III	Launched	4Q 2005
Exanta	thrombin inhibitor	prevention of stroke in AF	III	Filed	Filed*
Exanta	thrombin inhibitor	treatment of VTE	III	>2007	>2007
Exanta	thrombin inhibitor	arterial/post MI	II	>2007	>2007

*Discussions are ongoing with the FDA to determine if there is now a realistic prospect to bring Exanta to the US market. The IND file remains open.